



Complete Summary

GUIDELINE TITLE

Diagnosis and outpatient management of asthma.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis and outpatient management of asthma. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 Mar. 49 p. [31 references]

GUIDELINE STATUS

This is the current release of guideline.

This guideline updates a previous version: Diagnosis and management of asthma. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2003 May. 49 p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

On November 18, 2005, the U.S. Food and Drug Administration (FDA) notified manufacturers of Advair Diskus, Foradil Aerolizer, and Serevent Diskus to update their existing product labels with new warnings and a Medication Guide for patients to alert health care professionals and patients that these medicines may increase the chance of severe asthma episodes, and death when those episodes occur. All of these products contain long-acting beta2-adrenergic agonists (LABA). Even though LABAs decrease the frequency of asthma episodes, these medicines may make asthma episodes more severe when they occur. A Medication Guide with information about these risks will be given to patients when a prescription for a LABA is filled or refilled. See the [FDA Web site](#) for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

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EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Asthma

- Acute asthma
- Chronic asthma

GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Internal Medicine
Pediatrics
Pulmonary Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To promote the accurate assessment of asthma severity through the use of objective measures of lung function
- To promote long-term control of persistent asthma through the use of inhaled corticosteroid drug therapy
- To promote the partnership of patients with asthma and/or their parents with health care professionals through education and use of written action plans

TARGET POPULATION

Patients over 5 years of age who present with asthma-like symptoms or have been diagnosed with asthma

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnostic Assessments (at Initial Diagnosis and Interval Evaluations)

1. Medical history
2. Physical examination
3. Asthma triggers/allergens assessment
4. Pulmonary function tests: spirometry, including measurements of forced expiratory volume in 1 second (FEV₁), forced vital capacity (FVC), ratio of forced expiratory volume in 1 second to forced vital capacity (FEV₁/FVC), or peak expiratory flow rate (PEFR)
5. Additional clinical testing, such as oxygen saturation, arterial blood gases, chest x-ray, complete blood count with eosinophils, total immunoglobulin E, sputum exam, bronchial provocation tests, electrolytes, electrocardiogram, and evaluation for gastroesophageal reflux disease (GERD),
6. Assessment of asthma severity, based on frequency and severity of symptoms, frequency and severity of exacerbations, and spirometry measurements
7. Specialty consultation as indicated

Management of Acute Asthma

1. Review of history and physical exam
2. Treatment with beta₂-agonists or alternatives
3. Assessment of response based on pulmonary function tests and symptoms
4. Patient education and follow-up

Step Care of Pharmacologic Treatment

1. Annual influenza vaccination
2. Systemic corticosteroids
3. Cromolyn sodium and nedocromil
4. Long-acting beta₂-agonists
5. Methylxanthines
6. Leukotriene modifiers
7. Inhaled corticosteroids
8. Short-acting inhaled beta₂ -agonists in metered-dose and dry powder formulations
9. Anticholinergics

Asthma Education

1. Education in basic facts about asthma
2. Education in how medications work and the need for adherence
3. Education in inhaler technique
4. Written action plan, including home peak flow rate monitoring

5. Environmental control measures
6. Emphasis on regular follow-up visits and asthma treatment adherence

MAJOR OUTCOMES CONSIDERED

- Asthma symptom control
- Sensitivity and specificity of diagnostic tests
- Asthma morbidity measures such as level of physical activity, lost work days, unscheduled office visits, and emergency room and hospital admissions
- Side effects or complications of asthma pharmacotherapy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent, with minor exceptions at most. The results are free of significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is uncertainty attached to the conclusion because of inconsistencies among the results from different studies or

because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test

- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports

Class M:

- Meta-analysis
- Systemic review
- Decision analysis
- Cost-effectiveness study

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline draft, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member medical groups during an eight-week period of "Critical Review."

Each of the Institute's participating medical groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating medical groups following general implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group: Second Draft

Following the completion of the "Critical Review" period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary and a written response is prepared to address each of the suggestions received from medical groups. Two members of the Respiratory Steering Committee carefully review the Critical Review input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of two questions: (1) Have the concerns of the medical groups been adequately addressed? (2) Are the medical groups willing and able to implement the guideline? The committee then either approves the guideline for pilot testing as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Medical groups introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occurs throughout the pilot test phase, which usually lasts for six months. Comments and suggestions are solicited in the same manner as used during the "Critical Review" phase.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Respiratory Steering Committee reviews the revised guideline and approves it for implementation.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations for diagnosis and management of asthma are presented in the form of an algorithm, [Diagnosis and Outpatient Management of Asthma](#), with 10 components, accompanied by detailed annotations. Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) and key conclusions (I-III, Not Assignable) definitions are repeated at the end of the "Major Recommendations" field.

Clinical Highlights

1. Conduct interval evaluations of asthma including medical history and physical examination, assessment of asthma triggers and allergens, measurement of pulmonary function, and consideration of consultation and/or allergy testing. (Annotation #6)
2. Regularly assess asthma control. (Annotation #7)
3. Match medical intervention with asthma severity and adjust to correspond with change over time. (Annotation #8; see also Table 8A in original guideline document)
4. Achieve effective control of chronic persistent asthma through use of inhaled corticosteroid therapy. (See Table 8A in original guideline document)
5. Provide asthma education to patients and parents of pediatric patients. Education should include basic facts about asthma, how medications work, inhaler technique, a written action plan including home peak flow rate monitoring or a symptom diary, environmental control measures, and emphasis on the need for regular follow-up visits. (Annotation #9)

Diagnosis and Outpatient Management of Asthma Algorithm Annotations

1. Symptoms of Asthma

Symptoms suggestive of asthma include episodic wheezing and cough with nocturnal, seasonal, or exertional characteristics. Infants and children with frequent episodes of "bronchitis" are likely to have asthma. Atopic and positive family histories for asthma, particularly when associated with previously mentioned symptoms, should encourage one to consider a diagnosis of asthma.

Eliciting symptoms should emphasize characterizing the current classification scheme that describes frequency per week, changes in physical activity, diurnal variation, and seasonal variation. It is important to recognize that patients with asthma are heterogeneous, falling into every age group, from infancy to older age, and presenting a spectrum of signs and symptoms that vary in degree and severity from patient to patient as well as within an individual patient over time.

Evidence supporting this conclusion is of classes: M, R

2. Previous Diagnosis of Asthma?

Key Points:

- At each evaluation, it is important to consider whether or not a previous diagnosis was correct.
- History and physical consistent with diagnosis
- Diagnosis confirmed by spirometry
- Response to therapy consistent with symptoms

Evidence supporting this conclusion is of class: R

3. Establish Diagnosis of Asthma

Key Points:

- The diagnosis of asthma is based on the patient's medical history, physical examination, pulmonary function tests, and laboratory test results.
- Spirometry is recommended for the diagnosis of asthma.

A. Asthma triggers

1. Viral respiratory infections
2. Environmental allergens
3. Exercise, temperature, humidity
4. Occupational and recreational allergens or irritants
5. Environmental irritants (perfume, tobacco smoke, wood burning stoves)
6. Drugs (aspirin, nonsteroidal anti-inflammatory drugs [NSAIDs], beta blocker) and food (sulfites)

B. Other historical components

1. Emergency room visits and hospitalization
2. Medication use (especially oral steroids)
3. Lung function, peak expiratory flow rate (PEFR) variability
4. Associated symptoms (e.g., rhinitis, sinusitis, gastroesophageal reflux disease [GERD])

C. Clinical testing

1. Accurate spirometry is recommended in every patient 5 years of age or older at the time of diagnosis.
2. Additional studies done, tailored to the specific patient.
 - Allergy testing (skin testing, in vitro specific immunoglobulin E [IgE] antibody testing)
 - Chest radiography, to exclude alternative diagnosis
 - Bronchial provocation testing if spirometry is normal or near normal
 - Sinus x-rays or computed tomography (CT) scan
 - Gastroesophageal reflux disease (GERD) evaluation
 - Complete blood count (CBC) with eosinophils, total IgE, sputum exam

Spirometry is generally valuable in children 5 years of age or older; however some children cannot conduct the maneuver depending on developmental ability. Spirometry measurements (forced expiratory volume in 1 second [FEV₁], forced vital capacity [FVC], and the ratio of forced expiratory volume in 1 second to forced vital capacity [FEV₁/FVC]) before or after the patient inhales a short-acting bronchodilator should be undertaken for patients in whom the diagnosis of asthma is being considered. Airflow obstruction is indicated by reduced FEV₁ and FEV₁/FVC values relative to reference or predicted values. Significant reversibility is indicated by an increase of 12 percent or greater and 200 mL in FEV₁ after inhaling a short-acting bronchodilator.

Methacholine challenge testing may provide a useful confirmatory diagnostic test in patients with normal or near-normal spirometry. Investigation into the role of allergy, at least with a complete history, should be done in every patient, given high prevalence of positive skin tests among individuals with asthma and the benefits of limiting exposure to known allergens. Eosinophil count and IgE may be elevated in asthma; however, neither test has sufficient specificity or sensitivity to be used alone in a diagnosis. The chest x-ray and electrocardiogram are usually normal in asthma but may be useful to exclude other pulmonary or cardiac conditions. Sputum examination may be helpful if sputum eosinophilia or infection is suspected.

There are several clinical scenarios in children that have a frequent association with asthma and should strongly suggest asthma as a possible diagnosis. These include recurrent pulmonary infiltrates (especially right middle lobe infiltrates) that clear radiologically within two to three days, and the diagnosis of pneumonia without fever. Asthma may cause radiologic uncertainty since mucus plugging and atelectasis may be interpreted as infiltrates.

(See the original guideline document for additional information concerning differential diagnostic possibilities for asthma.)

4. Acute Asthma?

Symptoms of an acute asthma episode include progressive breathlessness, cough, wheezing, or chest tightness. An acute asthma episode is characterized by a decrease in expiratory airflow that can be documented and quantified by measurement of lung function (spirometry or PEFr). (Note that the algorithm is intended for treatment of outpatients. Critically ill patients are beyond the scope of this guideline. See the National Guideline Clearinghouse (NGC) summary of the Institute for Clinical Systems Improvement (ICSI) guideline [Emergency and Inpatient Management of Asthma](#).)

Indications for emergency care include:

- Peak flow less than 50% predicted normal
- Failure to respond to a beta agonist
- Severe wheezing or coughing
- Extreme anxiety due to breathlessness

- Gasping for air, sweaty, or cyanotic
- Rapid deterioration over a few hours
- Severe retractions and nasal flaring
- Hunched forward

5. Management of Acute Asthma

Key Points:

- Patients experiencing an acute asthma exacerbation need a focused history and physical examination and measurement of airflow.
- Treatment is begun with inhaled short-acting beta₂-agonists administered by meter dose inhaler (MDI)/spacer or nebulizer.
- Further intensification of therapy is based on severity, response, and prior history, but typically includes a short course of oral corticosteroids.
- Decision to hospitalize must be individualized.
- All patients should receive follow-up and short-term education.

The following is an outline of management:

Review history and physical exam, which may include:

- History
 - Severity of symptoms, limitations, and sleep disturbance
 - Duration of symptoms
 - Current medical treatment plan
 - Adherence to medical treatment plan
 - Rescue medication use
 - Recent use of short acting beta₂-agonists
 - Number of bursts of oral steroids in past year
 - Review Asthma Action Plan and daily charting of peak flows
 - Previous emergency room (ER) visits or hospitalization
 - Record triggers:
 - Upper respiratory infection (URI)
 - Bronchitis, pneumonia
 - Exposure to allergens or irritants
 - Exercise
- Physical exam
 - Vital signs
 - Auscultation of chest
 - FEV₁ or peak flow rate
 - O₂ saturation (pulse oximetry)
 - Use of accessory muscles
 - Alertness
 - Color
- Laboratory studies

Treatment with bronchodilators should not be delayed for laboratory studies. Tests which may be useful include:

- Arterial blood gases (ABGs)

- Chest x-ray (CXR)
- Complete blood count (CBC)
- Electrocardiogram (EKG)
- Electrolytes
- Theophylline concentration
- Assess severity

Assessment is based on history and physical exam.

Treatment

Usual initial treatment is with short-acting beta₂-agonist (albuterol) administered by nebulizer or MDI/spacer.

Alternatives:

Epinephrine: (1:1000)

- Adults: 0.3 to 0.5 mg subcutaneously or intramuscularly every 20 minutes up to 3 doses
- Pediatrics: 0.01 mg/kg up to 0.3 to 0.5 mg subcutaneously or intramuscularly every 20 minutes up to 3 doses

Ipratropium added to nebulized beta₂-agonist (albuterol)

- Nebulized dose for adults and those over 12 years of age is 0.5 mg every 4 hours. Not U.S. Food and Drug Administration (FDA)-approved for any indication in those under 12 years of age.
- Ipratropium is not currently FDA-approved for use in asthma.

Levalbuterol

- Dose for adolescents over 12 years of age and adults is 0.63 mg (via nebulizer) three times per day (TID) (every 6 to 8 hours); may increase to 1.25 mg via nebulizer TID (every 6 to 8 hours) if patient does not exhibit adequate response.
- Dose for children 6 to 11 years of age is 0.31 mg (via nebulizer) TID. Routine dosing should not exceed 0.63 mg TID.

Assess Response

Good Response

- Peak flow or FEV₁ greater than 70% predicted normal
- No wheezing on auscultation

Incomplete Response

- Peak flow or FEV₁ 50 to 70% predicted normal
- Mild wheezing
- Consider hospitalization, particularly for high-risk patients:

- Past history of sudden severe exacerbation
- Prior intubation for asthma
- Two or more hospitalizations for asthma in the past year
- Three or more emergency care visits for asthma within the past year
- Hospitalization or an emergency care visit for asthma within the past month
- Use of more than 2 canisters per month of inhaled short-acting beta₂-agonists
- Current use of systemic corticosteroids or recent withdrawal from systemic corticosteroids
- Difficulty perceiving airflow obstruction or its severity
- Comorbidity, as from cardiovascular disease or chronic obstructive pulmonary disease
- Serious psychiatric disease or psychosocial problems
- Low socioeconomic status and urban residence
- Illicit drug use
- Sensitivity to *Alternaria*

Poor Response

- Peak flow or FEV₁ less than 50% predicted normal
- No improvement in respiratory distress
- Strongly consider hospitalization
- Continue inhaled beta₂-agonist every 60 minutes
- Start oral prednisone unless contraindicated
 - Adult: short course "burst" 40 to 60 mg/day as single or 2 divided doses for 3 to 10 days
 - Pediatric: short course "burst" 1 to 2 mg/kg day in 2 divided doses, maximum 60 mg/day for 3 to 10 days

Home Treatment and Revised Asthma Action Plan

Medications

- Inhaled beta₂-agonist every 2 to 6 hours
- Initiate or increase anti-inflammatory medication:
 - Inhaled corticosteroids
 - Cromolyn/nedocromil
 - Consider leukotriene modifiers
- Strongly consider systemic corticosteroids in patients with acute asthma exacerbation. Corticosteroids aid symptom resolution and prevent asthma relapse.
- Antibiotics are not recommended for the treatment of acute asthma except for those patients with signs of acute bacterial infection, fever, and purulent sputum.

Education

- Teach or check inhaler technique/teach nebulizer use
- Explain medications
- Review action plan

- Monitor peak flow
- Reinforce trigger control

Follow-up

- All patients need return appointment for management of asthma
- Review and discuss signs or symptoms requiring emergent care

Evidence supporting this conclusion is of classes: A, M, R

6. Interval Evaluation

Interval evaluation of asthma should include the following:

- Medical history
- Assess asthma triggers/allergens
- Physical examination
- Measure pulmonary function.
- Consider specialty consultation.

Medical History

- Disruption of usual activities (work, school, home)
- Sleep disturbance
- Level of usage of short-acting beta₂-agonist
- Adherence to medical treatment plan
- Interval exacerbation of symptoms (either treated by self or a health care provider)
- Symptoms suggesting comorbid conditions or alternative diagnosis
- Side effects of medications

Reassessment of medical history can elicit factors that affect overall asthma control and sense of well-being. The key symptoms that should alert the clinician include disruptive daytime symptoms and disturbances of sleep. It is also the consensus of the Expert Panel that symptoms early in the morning that do not improve fifteen minutes after short-acting beta₂-agonist that is being used should be discussed, since overuse can be a marker of the potentially fatality prone asthmatic. The use of a quality of life tool or questionnaire can assist to elicit history.

Evidence supporting this conclusion is of classes: C, D

Assess Asthma Triggers/Allergens

- Inquire about exposure to triggers and allergens (e.g., occupational, pets, smoke).
- Allergy testing is recommended for patients with persistent asthma who are exposed to perennial indoor allergens.

Evidence supporting this conclusion is of classes: A, C, D

Physical Examination

- Assess signs associated with asthma, concurrent illness, or medication side effects.
- Height in children
- Head, eyes, ears, nose, throat, lungs, heart, skin

It is important to discuss any potential medication side effects as this often has a direct relationship to compliance. Common side effects from inhaled steroids include oral candidiasis and dysphonia. Beta₂-agonists may cause tachycardia, tremor, or nervousness. Individuals on long-term oral corticosteroids or frequent bursts of steroids need to be monitored for complications of corticosteroids use such as osteoporosis, hypertension, diabetes, and Cushing's syndrome.

The height of individuals on corticosteroids should be monitored over time. The potential effect on linear growth in children is important because these drugs tend to be used over long periods of time. Cumulative data in children suggest that low-to-medium doses of inhaled corticosteroids may have the potential of decreasing growth velocity, but this effect is not sustained in subsequent years of treatment, is not progressive, and may be reversible.

Inhaled glucocorticoids used to treat asthma have been shown to have deleterious effects on bone mineral density and markers of bone mineral metabolism. The risk of fracture attributable to inhaled or nasal glucocorticoids is uncertain.

The remainder of the physical exam either supports or refutes conditions and comorbidities discussed above (see history).

Evidence supporting this conclusion is of classes: A, M

Measure Pulmonary Function

It is important to measure pulmonary function at each follow-up visit. The two main methods are spirometry and peak expiratory flow rate (PEFR). Spirometry is more precise and yields more information than PEFR. It is helpful to verify the accuracy of the peak flow meter. It is useful when certain physical limitations affect accuracy of PEFR (example - very young or elderly, neuromuscular or orthopedic problems).

Spirometry recommended:

- For initial diagnosis or to reassess or confirm diagnosis
- After treatment is initiated or changed, and once symptoms and PEFR have stabilized to document attainment of "near normal pulmonary function"
- At least every 1 to 2 years to assess maintenance of airway function; more often as severity indicates

Regular monitoring of pulmonary function is particularly important for asthma patients who do not perceive their symptoms until obstruction is severe.

PEFR:

- Used for follow-up, not for diagnosis

PEFR provides a simple, quantitative, and reproducible measure of severity of airflow obstruction. The results are more reliable if the same type, and preferably the patient's own, meter is used.

During interval assessment the clinician should question the patient and review records to evaluate the frequency, severity, and causes of exacerbation. Triggers that may contribute should be reviewed. All patients on chronic maintenance medication should be questioned about exposure to inhalant allergens.

Evidence supporting this conclusion is of class: C, R

Consider Specialty Consultation

- Adults with severe persistent asthma, consider for moderate persistent asthma
- Children with moderate to severe persistent asthma, consider for mild persistent asthma
- Poorly controlled or complex asthma including previous life-threatening asthma exacerbation, or asthma exacerbations requiring more than 2 bursts of oral corticosteroids in 1 year, or asthma complicated by other medical or psychosocial conditions
- Additional diagnostic evaluations and/or testing (e.g., allergy skin testing, bronchoprovocation)
- Allergy testing is recommended for patients with persistent asthma who are exposed to perennial indoor allergens
- Evaluation and treatment of allergy (e.g., address occupation-related asthma, environmental counseling, immunotherapy)
- Patients who require additional or intensive asthma education not otherwise available
- For patients with moderate to severe persistent asthma, who are exposed to perennial indoor allergens, Omalizumab is available. They should be managed by an allergy specialist.

Referral to an asthma specialist should be considered when a patient's symptoms are severe or are not responding to standard care. Referral is also necessary when specialized testing, such as allergy testing or bronchoprovocation, are needed. There is evidence that referral to an asthma specialist can reduce repeat visit to the emergency room.

Evidence supporting this conclusion is of class: C

7. Assess Asthma Severity

The classification of asthma as mild intermittent, mild persistent, moderate persistent, or severe persistent is based on the clinical characteristics as well as objective assessment of lung function through FEV₁ or peak flow monitoring. The presence of one of the features of severity is sufficient to place a patient in that category and an individual's classification may change over time. Patients at any level of severity can have mild, moderate, or severe exacerbations. Some patients with intermittent asthma experience severe and life-threatening exacerbations separated by long periods of normal lung function and no symptoms.

Step 1: Mild Intermittent

- Symptoms twice a week or less
- Asymptomatic and normal peak expiratory flow (PEF) between exacerbations
- Exacerbations are brief (few hours to a few days)
- Nighttime symptoms twice a month or less
- FEV₁ or PEF 80% predicted or greater and PEF variability 20% predicted or less

Step 2: Mild Persistent

- Symptoms twice a week or more but once a day or less
- Exacerbations may affect activity
- Nighttime symptoms twice a month or more
- FEV₁ or PEF 80% predicted or greater and PEF variability 20 to 30% predicted

Step 3: Moderate Persistent

- Daily symptoms
- Daily use of inhaled short-acting beta₂-agonists
- Exacerbations affect activity
- Exacerbations twice a week or more; may last days
- Nighttime symptoms once a week or more or 4 times per month
- FEV₁ or PEF between 60 and 80% predicted
- PEF variability 30% or greater

Step 4: Severe Persistent

- Continual symptoms
- Limited physical activity
- Frequent exacerbations
- Frequent nighttime symptoms
- FEV₁ or PEF 60% predicted or less and PEF variability 30% predicted or greater

Evidence supporting this conclusion is of classes: M, R

8. Step Care of Pharmacologic Treatment

Key Points:

- Achieve effective control of chronic persistent asthma through use of inhaled corticosteroid therapy.

The aim of asthma therapy is to maintain control of asthma with the least amount of medication and hence minimize the risk for adverse effects. The stepwise approach to therapy in which the dose and number of medications and frequency of administration are increased as necessary and decreased when possible is used to achieve this control. Since asthma is a chronic inflammatory disorder of the airways with recurrent exacerbations, therapy for persistent asthma emphasizes efforts to suppress inflammation over the long-term and prevent exacerbations.

Based on data comparing leukotriene receptor antagonists (LTRAs) to inhaled corticosteroids, inhaled corticosteroids are the preferred treatment option for mild persistent asthma in adults, and by extrapolation until published data become available, for children. LTRAs are an alternative--although not preferred--treatment.

[Conclusion Grade I: See Conclusion Grading Worksheet -- Appendix A - Annotation #8 (Leukotriene Receptor Antagonists [LTRAs]) in the original guideline document.]

Managing asthma during pregnancy is the same treatment used for non-pregnant asthma patients.

NOTE: Annual influenza vaccinations are recommended for patients with persistent asthma.

Evidence supporting this conclusion is of classes: A, M, R

Stepwise Approach for Managing Asthma in Adults and Children Older than 5 Years of Age	
Step	Long-Term Control
Step 1 - Mild Intermittent <ul style="list-style-type: none">• Symptoms ≤ 2 times a week• Asymptomatic and normal PEF between exacerbations• Exacerbations are brief (few hours to a few days)• Nighttime symptoms ≤ 2 times a month• FEV_1 or PEF $\geq 80\%$ predicted and PEF variability $\leq 20\%$	No daily medications needed

Stepwise Approach for Managing Asthma in Adults and Children Older than 5 Years of Age	
Step	Long-Term Control
<p>Step 2 - Mild Persistent</p> <ul style="list-style-type: none"> • Symptoms ≥ 2 times a week but ≤ 1 time a day • Exacerbations may affect activity • Nighttime symptoms ≥ 2 times a month • FEV₁ or PEF ≥ 80 percent predicted and PEF variability 20 to 30% 	<p>Daily medication:</p> <ul style="list-style-type: none"> • Inhaled corticosteroids (low dose) (preferred) <p>OR</p> <ul style="list-style-type: none"> • Leukotriene modifiers, theophylline, nedocromil, or cromolyn
<p>Step 3 - Moderate Persistent</p> <ul style="list-style-type: none"> • Daily symptoms • Daily use of inhaled short-acting beta₂-agonists • Exacerbation affects activity • Exacerbations > 2 per week, may last days • Nighttime symptoms > 1 time a week • FEV₁ or PEF $\geq 60\%$ - $\leq 80\%$ predicted • PEF variability $\geq 30\%$ 	<p>Daily medications:</p> <ul style="list-style-type: none"> • Inhaled corticosteroid (low or medium dose) plus inhaled long-acting beta₂-agonist (preferred) <p>OR</p> <ul style="list-style-type: none"> • Inhaled corticosteroid (medium dose) plus leukotriene modifier, theophylline, or oral long-acting beta₂-agonist
<p>Step 4 - Severe Persistent</p> <ul style="list-style-type: none"> • Continual symptoms • Limited physical activity • Frequent exacerbations • Frequent nighttime symptoms • FEV₁ or PEF $\leq 60\%$ and PEF variability $\geq 30\%$ 	<p>Daily medications:</p> <ul style="list-style-type: none"> • Inhaled corticosteroid (medium dose or high dose) • PLUS: Long-acting beta₂-agonist (preferred) <p>and/OR Leukotriene modifier</p> <p>and/OR Theophylline</p> <p>Recommended for uncontrolled asthma:</p> <ul style="list-style-type: none"> • Oral corticosteroids (see Table 8D in original guideline document)
Step down:	Step up:

Stepwise Approach for Managing Asthma in Adults and Children Older than 5 Years of Age	
Step	Long-Term Control
Review treatment every 1 to 6 months; a gradual stepwise reduction in treatment may be possible.	If control not maintained, consider step up. First review patient medication technique, adherence, and environmental control (avoidance of allergens or other factors that contribute to asthma severity).
<p>Quick relief:</p> <ul style="list-style-type: none"> • Short-acting bronchodilator: inhaled beta₂-agonists as needed for symptoms with MDI spacer/holding chamber • Intensity of treatment will depend on severity of exacerbation. • Use of short-acting inhaled beta₂-agonists on a daily basis, or increasing use, indicates the need for additional long-term control therapy. 	
<p>Education:</p> <p>Step 1:</p> <ul style="list-style-type: none"> • Teach basic facts about asthma. • Teach inhaler/spacer/holding chamber technique. • Discuss role of medications. • Develop self-management plan. • Develop action plan for when and how to take rescue actions, especially for patient with a history of severe exacerbations. • Discuss appropriate environmental control measures to avoid exposure to known allergens and irritants. <p>Step 2:</p> <ul style="list-style-type: none"> • Teach self-monitoring. • Refer to group education if available. • Review and update self-management plan. <p>Step 3:</p> <p>Refer to individual education/counseling.</p>	

Refer to Tables 8B through 8D in the original guideline document for a detailed discussion of usual dosages for long-term medications, estimated comparative daily dosage for inhaled corticosteroids, and usual dosages for quick-relief medications.

9. Asthma Education

Key Points:

- Patient education is essential for successful management of asthma. It should begin at the time of diagnosis and be ongoing.

Patient education includes basic facts about asthma, how medications work and the need for adherence, inhaler technique, written action plan including home peak flow monitoring, environmental control measures, and emphasizing need for regular follow-up visits and asthma treatment adherence.

Supervised self-management (using patient education and adjustments of anti-inflammatory medication based on PEF or symptoms coupled with regular medical review, utilization of adherence to medication) reduces asthma morbidity. This reduction includes lost work days, unscheduled office visits, and emergency room (ER) and hospital admissions. [Conclusion Grade I : See Conclusion Grading Worksheet -- Appendix B - Annotation #9 (Asthma Education) in the original guideline document]

A sample Asthma Action Plan is attached in Annotation Appendix A of the original guideline document.

Evidence supporting this conclusion is of classes: A, M, R

10. Schedule Regular Follow-up Visits

Asthma is a chronic inflammatory lung disease and all chronic diseases need regular follow-up visits. Practitioners need to assess whether or not control of asthma has been maintained and if a step down in therapy is appropriate. Further, practitioners need to monitor and review the daily self-management and action plans, the medications, and the patient's inhaler and peak flow monitoring techniques.

The exact frequency of clinician visits is a matter of clinical judgment.

<u>Severity</u>	<u>Regular Follow-up Visit</u>
Mild intermittent	6 to 12 months
Mild persistent	6 months
Moderate persistent	3 months
Severe persistent	1 to 2 months and as often as needed to establish control

Definitions:

Classes of Research Reports

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports

Class M:

- Meta-analysis
- Systemic review
- Decision analysis
- Cost-effectiveness study

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

Conclusion Grades

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence that directly supports or refutes the conclusion.

CLINICAL ALGORITHM(S)

A detailed and annotated clinical algorithm is provided in the original guideline document for [Diagnosis and Outpatient Management of Asthma](#).

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline contains an annotated bibliography and discussion of the evidence supporting each recommendation. The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations (i.e., choice among alternative therapeutic approaches) is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Accurate diagnosis and assessment of asthma severity through the use of objective measures of lung function
- Effective long-term control of persistent asthma through the use of inhaled corticosteroid drug therapy
- Effective partnership of patients with asthma and/or their parents with health care professionals through education and the use of written action plans

POTENTIAL HARMS

Risk of Adverse Effects Associated with Asthma Pharmacotherapy

- Common side effects from inhaled steroids include oral candidiasis and dysphonia.
- Inhaled glucocorticoids used to treat asthma have been shown to have deleterious effects on bone mineral density and markers of bone mineral

- metabolism. The risk of fracture attributable to inhaled or nasal glucocorticoids is uncertain.
- Beta₂-agonists may cause tachycardia, tremor, or nervousness.
 - Individuals on long-term oral corticosteroids or frequent bursts of steroids need to be monitored for complications of corticosteroid use such as osteoporosis, hypertension, diabetes, and Cushing's syndrome.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the valuation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This clinical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms
Clinical Algorithm
Patient Resources

Pocket Guide/Reference Cards Quality Measures

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED NQMC MEASURES

- [Diagnosis and outpatient management of asthma: percentage of patients with asthma with spirometry or peak flow meter reading documented in the medical record at the last visit.](#)
- [Diagnosis and outpatient management of asthma: percentage of children with persistent asthma who are on inhaled corticosteroids medication.](#)
- [Diagnosis and outpatient management of asthma: percentage of adults with persistent asthma who are on inhaled corticosteroids medication.](#)
- [Diagnosis and outpatient management of asthma: percentage of patients with asthma with education about asthma documented in the medical record.](#)

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis and outpatient management of asthma. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 Mar. 49 p. [31 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

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1998 Jun (revised 2005 March)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

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GUIDELINE COMMITTEE

Respiratory Steering Committee

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In the interest of full disclosure, Institute for Clinical Systems Improvement (ICSI) has adopted a policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers. Readers of the guideline may assume that only work group members listed below have potential conflicts of interest to disclose.

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GUIDELINE STATUS

This is the current release of guideline.

This guideline updates a previous version: Diagnosis and management of asthma. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2003 May. 49 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the [Institute for Clinical Systems Improvement \(ICSI\) Web site](http://www.icsi.org).

PATIENT RESOURCES

The following is available:

- Diagnosis and outpatient management of asthma. Bloomington (MN): Institute for Clinical Systems Improvement, 2005 Apr.

Electronic copies: Available from the [Institute for Clinical Systems Improvement \(ICSI\) Web site](http://www.icsi.org).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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